

### **REMARKS**

Applicant's attorneys submitted an amendment in response to the Office Action dated March 26, 2002 on June 26, 2002 and a supplemental amendment on July 24, 2002 to correct certain typographical errors, errors in claim dependency, and errors made in the Marked-Up Version of the Claims. In Paper No. 15, mailed November 5, 2002, the Examiner notified Applicant that the amendments made the record confusing and requested Applicant cancel all pending claims and resubmit all its intended changes as new claims.

Applicant therefore has cancelled all pending claims added new claims 20 – 37. For the convenience of the Examiner, the Applicant has also repeated herein its remarks regarding the art cited in the Examiner's rejection Office Action dated March 26, 2002. No new matter has been added by this Amendment.

#### **Rejection Under 35 U.S.C. §112**

Applicant submits that Claims 20 – 37 filed herewith comply with 35 U.S.C. § 112, second paragraph.

#### **Rejection Under 35 U.S.C. §102**

Claim 1 has been rejected under 35 U.S.C. § 102(b) as anticipated by a published PCT application with international publication number WO 98/08500. This rejection is respectfully traversed.

PCT application WO 98/08500 discloses hypertonic arginine formulations used in treating hemorrhagic shock. The disclosure focuses on L-arginine by fully discussing the benefits of L-arginine and various formulations in which it has been the ingredient of interest, with all other ingredients meriting no discussion. All of the disclosed methods and claims require L-arginine as an essential component. For instance, WO 98/08500 discloses seven examples, all of which illustrate the effects of various solutions containing L-arginine. Example 5 particularly "shows several hypertonic arginine formulations that will be useful for treatment of trauma and shock" with one formulation including L-arginine, sodium chloride and hetastarch. Furthermore, Claims 1-16 all contain L-arginine. Neither the disclosure nor the claims disclose NaCl and hetastarch in combination with any substance other than L-arginine, as effective in the

treatment of hemorrhagic shock. In contrast, new independent claim 20, recites a composition that is free of L-arginine.

Because WO 98/08500 does not disclose a pharmaceutical composition without L-arginine as a component, it is respectfully requested new independent claim 20 be allowed.

### **Rejection Under 35 U.S.C. §103**

Claims 1-7 have been rejected under 35 U.S.C. § 103(a) as anticipated by a published PCT application with international publication number WO 98/08500. This rejection is respectfully traversed.

WO 98/08500 remains deficient as a reference, as it does not teach a pharmaceutical composition without L-arginine as recited in new claims 20-37. The Examiner ignores the absence of L-arginine in the instant invention in making his suggestions of obviousness. Every formulation disclosed in WO 98/08500 contains L-arginine. WO 98/08500 does not suggest that L-arginine could be eliminated from the formulation without rendering the formulation ineffective. In fact, eliminating L-arginine would destroy the teachings of WO 98/08500, as it is concerned entirely with using L-arginine in various formulations with other compounds.

In addition to teaching away from the absence of L-arginine in the pharmaceutical composition, WO 98/08500 fails to disclose or suggest all the elements of the dependent claims. For example, WO 98/08500 discloses a 7.5% hypertonic saline solution. WO 98/08500 does not suggest how far the concentration of that solution might be lowered nor does it suggest any alternative specific amounts of NaCl in the formulations it does disclose. WO 98/08500 therefore particularly fails to disclose or suggest a solution having between about 2.5 and 2.7 g NaCl as recited in new claim 21. Furthermore, WO 98/08500 fails to disclose or suggest any of the elements in all of the new claims 20-37, such as dextran, carboxymethyl starch, PVP, gelatin derivatives, condensed glucose, glucose, fructose, lactose, glycerin, xylitol, sodium alginate, N-2-hydroxypropylacrylamide, ethylene epoxide, polypropylene glycol, pectin, or pentahydroxyethyl starch.

It is therefore respectfully requested that new claims 20-37 be allowed as being patentable over WO 98/08500.

### CONCLUSION

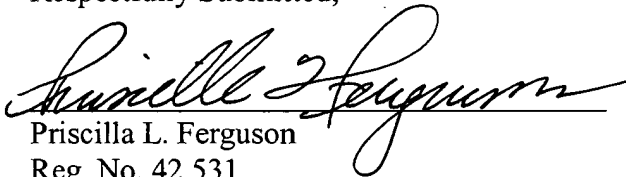
In view of the foregoing amendment and remarks, Applicant submits that all of the claims now present are allowable, and withdrawal of the rejections and a Notice of Allowance are courteously solicited.

If any impediment to the allowance of the claims remains after consideration of this amendment, and such impediment could be alleviated during a telephone interview, the Examiner is invited to telephone the undersigned at (214) 969-4657 so that such issues may be resolved as expeditiously as possible.

If any applicable fee or refund has been overlooked, the Commissioner is hereby authorized to charge any fee or credit any refund to the deposit account of Akin, Gump, Strauss, Hauer & Feld, L.L.P., No. 01-0657.

Respectfully Submitted,

Date: November 26, 2002

  
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